UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,581	02/18/2004	Liam Seery	8912/2015	2809

29933 7590 06/13/2006

PALMER & DODGE, LLP
KATHLEEN M. WILLIAMS
111 HUNTINGTON AVENUE
BOSTON, MA 02199

EXAMINER	
BORGEEST, CHRISTINA M	

ART UNIT	PAPER NUMBER
1649	

DATE MAILED: 06/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,581	SEERY ET AL.	
	Examiner	Art Unit	
	Christina Borgeest	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12* is/are pending in the application.

4a) Of the above claim(s) *4-12* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *18 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Formal Matters

The Examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Examiner Christina Borgeest, Ph.D., Art Unit 1649.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-3) and the species inositol-1,4 5-triphosphate 3-kinase (SEQ ID NO: 226) in the replies filed on 23 January 2006 and 3 May 2006 is acknowledged. The traversal is on the ground(s) that Applicants disagree with the basis of the restriction requirement. Furthermore the previous examiner required if that if the elected sequence is a cytoplasmic kinase, then Applicants must elect between assays using a purified enzyme and those using expression of the enzyme within a cell, because the assays utilize different products and require separate searches. Applicants disagree because the claims require providing the elected protein (as shown in SEQ ID NO: 226), contacting it with a test agent, and detecting the presence or absence of a signal generated from the interaction and they are based on the detection of an interaction of the kinase as shown in SEQ ID NO: 226 and a test agent; whether or not that occurs using an isolated enzyme or enzyme expressed in a cell does not impact the search burden of the examiner, because art teaching either species would anticipate the claim. Furthermore Applicants

argue that the assays do not utilize different products and do not require separate searches. Moreover, the Examiner has not provided any rationale as to why the two alleged species (isolated vs. cell expressed) are patentably distinct so as to necessitate further restriction. These arguments are found partially persuasive. While the examiner maintains that a screening method comprising contacting SEQ ID NO: 226 (inositol-1,4 5-triphosphate 3-kinase) with a test agent, and detecting the presence or absence of a signal generated from the interaction is a separate and distinct invention from screening methods based on interactions with test agents and other proteins, the argument that art teaching either an isolated enzyme or an enzyme expressed in the cell would anticipate or obviate the claims is persuasive. Thus claims 1-3 will be examined insomuch as they pertain to a method of identifying an agent that modulates inositol-1,4 5-triphosphate 3-kinase comprising providing a preparation containing inositol-1,4 5-triphosphate 3-kinase; incubating the preparation with a test agent to be screened under conditions to permit binding of the test agent to inositol-1,4 5-triphosphate 3-kinase; determining whether the test agent interacts with the protein by detecting the presence or absence of a signal generated from the interaction of the agent with the protein and determining whether the test agent modulates the function of inositol-1,4 5-triphosphate 3-kinase by detecting a change in the phosphotransferase activity of inositol-1,4 5-triphosphate 3-kinase, wherein the preparation containing inositol-1,4 5-triphosphate 3-kinase comprises a cell that expresses inositol-1,4 5-triphosphate 3-kinase.

The requirement is still deemed proper and is therefore made FINAL.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in the United Kingdom on 23 January 2003. It is noted, however, that applicant has not filed a certified copy of the 0301566.6 application as required by 35 U.S.C. 119(b).

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code at paragraphs [0335] and [0627]. See MPEP § 608.01.

In addition, Table 1B refers to the proteins by GenBank number. Because a GenBank number can change, it is improper to refer to proteins in this way. Proteins should be identified by SEQ ID NO.

Claim Objections

Claims 1-3 are objected to because of the following informalities: The claims recite "[a] method of identifying an agent that modulates the function of an apoptosis associated protein that is encoded by a gene selected from Table IB...," thus the claims encompass non-elected subject matter. Appropriate correction is required.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are incomplete because they do not refer to a sequence listing (SEQ ID NO: 226). Appropriate correction is required to overcome this claim. In addition, claims should not refer to a table in a claim unless it is absolutely necessary. See MPEP 2173.05(s):

> Where possible, claims are to be complete in themselves. Incorporation by reference to a specific figure or table "is permitted only in exceptional circumstances where there is no practical way to define the invention in words and where it is more concise to incorporate by reference than duplicating a drawing or table into the claim. Incorporation by reference is a necessity doctrine, not for applicant's convenience." Ex parte Fressola, 27 USPQ2d 1608, 1609 (Bd. Pat. App. & Inter. 1993) (citations omitted).

Claim Rejections - 35 USC § 112, first paragraph

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling a method of identifying an agent that modulates ***the full length of the protein*** encoded by the gene for inositol 1,4,5-triphosphate 3-kinase C, does not reasonably provide enablement for a method of identifying an agent that modulates ***the protein fragment*** as shown in SEQ ID NO: 226. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." (See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 Fed. Cir. 1988) These factors include, but are not limited to: (a) the breadth of the claims; (b) the nature of the invention; (c) the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The elected protein encoded by the sequence shown in SEQ ID NO: 226 is a fragment of human inositol 1,4,5-triphosphate 3-kinase C (ITPKC). The claims recite a screening method for identifying an agent that modulates the function of SEQ ID NO: 226 comprising providing a preparation containing SEQ ID NO: 226, incubating the preparation with a test agent to be screened under conditions that permit binding of the test agent to SEQ ID NO: 226, and determining whether the test agent interacts with SEQ ID NO: 226 by determining phosphotransferase activity of the protein kinase. Dewaste et al. (Biochem J. 2000; 352: 343-351) cloned and expressed ITPKC in bacterial and COS-7 cells. At p. 345, Figure 2 (left column), the deduced amino acid sequence of ITPKC is shown with putative phosphorylation sites doubly underlined. SEQ ID NO: 226 is a 137 amino acid fragment of ITPKC (from residue 531 to 667 of the deduce amino acid sequence shown in Figure 2). The fragment of ITPKC shown by SEQ ID NO: 226 lacks all of the putative phosphorylation sites as reported by Dewaste

et al. It is not clear how phosphorylation activity could be measured (as is required by the claims using the elected protein fragment as shown by SEQ ID NO: 226. Furthermore, although the binding site of ATP is included in the elected protein fragment (SEQ ID NO: 226), neither the MDCK, part of the Ins(1,4,5)P_3 inositol phosphate binding motif that is conserved in this family of kinases in mammals and yeast, nor the calmodulin binding site are included in the elected protein fragment (SEQ ID NO: 226).

Due to the lack of direction/guidance presented in the specification regarding how a fragment (SEQ ID NO: 226) of ITPKC lacking essential regions could be used in the claimed screening methods, the absence of working examples directed to the same, and the contradictory state of the prior art (see Dewaste et al., cited above), undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Dewaste et al. (cited above under Rejections under 35 U.S.C., first paragraph). The claims recite a screening method for identifying an agent that modulates the function of SEQ ID NO:

226 comprising providing a preparation containing SEQ ID NO: 226, wherein the preparation containing the protein comprises a cell expressing the protein shown in SEQ ID NO: 226, incubating the cell expressing the protein in SEQ ID NO: 226 with a test agent to be screened under conditions that permit binding of the test agent to SEQ ID NO: 226, and determining whether the test agent interacts with SEQ ID NO: 226 by determining phosphotransferase activity of the protein kinase. Dewaste et al. teach a method of expressing ITPKC in both *E. coli* and COS-7 cells (i.e., preparation containing SEQ ID NO: 226, wherein the preparation containing the protein comprises a cell expressing the protein—see p 344, right column, last paragraph and p. 345, left column, last paragraph), treating with Ca2+ (i.e., test agent—see p. 348, right column, 2nd paragraph) and measuring kinse activity (i.e., determining phosphotransferase activity of the protein kinase—see p. 349, Figure 8). Note that the open language of the claims, "protein that is encoded by a gene selected from Table 1B", is encompassed by the full length ITPKC taught by Dewaste et al., thus the claims are encompassed by the teachings of Dewaste et al., and do not contribute anything over the prior art.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Cotter et al. (WO 02/04657—citation 1 on IDS form submitted 1 June 2004) describes the neutrophil model cell system that is the basis of a discovery assay associated with inhibition of apoptosis (see p. 25, lines 10-20).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christina Borgeest whose telephone number is 571-272-4482. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christina Borgeest, Ph.D.

JANET L. ANDRES
SUPERVISORY PATENT EXAMINER